MANUFACTURING AND SUPPLY AGREEMENT

by and among

COLLINGWOOD PHARMACEUTICALS, INC.,

and

OVAMED GMBH

March 29, 2006

TABLE OF CONTENTS

1.	DEFI	NITIONS	•
2.	MAN	UFACTURING AND SUPPLY AND PURCHASE.	
	2.1.	Manufacturing	
	2.2.	Manufacturing Facilities	
	2.3.	Third Party Manufacturers.	*******
	2.4.	Purchase Orders	
	2.5.	Inspection and Notifications.	
	2.6.	Semi-Annual Relationship Review.	
	2.7.	Documentation.	٠٠٠٠٠٠٠
3.	DELI	VERY, ACCEPTANCE, REJECTIONS.	٠٠٠٠٠٠٠
	3.1.	<u>Delivery</u>	٠٠٠٠٠٠٠
	3.2.	Acceptance and Rejection.	
	3.3.	Late Delivery Credit.	
4.	RECA	LLS, ADVERSE EVENT REPORTING, COMPLAINTS; REGULATORY	
	4.1.	Recalls.	
	4.2.	Adverse Experience Reporting.	16
	4.3.	Complaints.	11
	4.4.	Regulatory Approvals.	11
5.	QUAI	LITY AND CAPACITY.	11
•	5.1.	Ovamed Representations, Warranties and Covenants.	11
	5.2.	Testing of Product for Conformance with Specifications.	12
6.	CHAI	NGES IN SPECIFICATIONS OR MANUFACTURING PROCEDURES.	17
	6.1.	Sponsored Changes.	12
	6.2.	Impact on Inventory.	13
7.	PAYN	AENT.	13
	7.1.	Price.	13
	7.2.	Milestone Credit.	14
	7.3.	Payment	14
8.	TERM	I AND TERMINATION.	14
	8.1.	<u>Term</u>	14
	8.2.	Termination	15
	8.3.	Survival.	17
9.	INDE	MNIFICATION AND INSURANCE	17
	9.1.	Ovamed Indemnification of Paramount.	17
	9.2.	Paramount Indemnification of Ovamed.	17
	9.3.	<u>Insurance</u> .	
10.		LITY	19
11.	INTEI	LECTUAL PROPERTY.	19
•	11.1.	Ownership of Intellectual Property.	19
	11.2.	Cooperation	19
	11.3.	License of Ovamed Intellectual Property Rights.	20
12.	CONF	IDENTIAL INFORMATION.	20
		Confidentiality.	

	12.2.	Authorized Disclosure.	20
•	12.3.	No Confidential Information of Other Parties.	
	12.4.		
13.	MISC	ELLANEOUS.	21
	13.1.	Correspondence and Notices	
	13.2.	Compliance with the Laws; Permits and Licenses.	
	13.3.	Assignment.	
	13.4.	Force Majeure.	23
	13.5.	Use of Name.	23
	13.6.	Language of the Agreement.	
	13.7.	UN Convention on Contracts for Sale of Goods.	
	13.8.	<u>Amendment</u>	
	13.9.	Waiver.	
	13.10.	Severability.	24
	13.11.	Descriptive Headings.	24
	13.12.	Governing Law.	24
		Jurisdiction; Venue; Service of Process.	
		Entire Agreement.	
	13.15.	Conflicts	25
	13.16.	Independent Contractors.	25
		Counterparts.	
	•		

SCHEDULES AND EXHIBITS

Exhibit A Specifications

Exhibit B Work to be Performed

Exhibit C [Raw Materials Index]

Exhibit D Form of certificate of analysis

Exhibit E Clinical Plan for the Product

MANUFACTURING AND SUPPLY AGREEMENT

This Manufacturing and Supply Agreement (the "<u>Agreement</u>") is entered into this __day of December, 2005 (the "<u>Effective Date</u>"), by and between Collingwood Pharmaceuticals, Inc., a corporation organized and existing under the laws of Delaware and having a principal place of business at 787 Seventh Avenue, 48th Floor, New York, New York 10019 ("<u>Collingwood</u>"), and Ovamed GmbH, a corporation organized and existing under the laws of Germany and having a principal place of business at Kiebitzhörn 33-35, 22885 Barsbüttel, Germany ("<u>Ovamed</u>"). Collingwood and Ovamed may each be referred to herein individually as a "<u>Party</u>" and collectively as the "<u>Parties</u>."

Recitals

- A. Collingwood wishes to engage Ovamed to manufacture Products (as defined below) and supply them to Collingwood as an active pharmaceutical ingredient and drug product for preclinical, clinical and commercial use.
- B. Ovamed desires to manufacture Products and supply them to Collingwood and Collingwood desires to purchase Products from Ovamed for such use as further described and in accordance with the terms and conditions of this Agreement.
- C. Ovamed has obtained an exclusive license (the "<u>License</u>") from the University of Iowa Research Foundation ("<u>UIRF</u>") to practice certain patent rights in the United States, Canada, Japan, and Australia;
- D. Collingwood and Ovamed have entered an Exclusive Sublicense Agreement (The "Sublicense"), under which Ovamed granted to Collingwood an exclusive right to practice the patent rights discussed in the License in connection with the prevention, treatment, cure or diagnosis of human diseases, with the exception of gastroenterology (e.g., inflammatory bowel disease) and hepatology in Europe (the "Field of Use").

Agreement

NOW THEREFORE, the parties agree as follows:

1. DEFINITIONS

Capitalized terms used but not defined in this Agreement have the meanings given to them as set forth below.

- "Acceptance" has the meaning given to it in Section 3.2.1.
- "Approved Subcontractor" means, at any time, any member of the Ovamed Group or other subcontractor engaged by Ovamed for the manufacture or supply of a principal component necessary for the manufacture of Product reasonably acceptable to Collingwood.
- "Affiliate" of any person shall mean any general or limited partner of any such person that is a partnership, member of any such person that is a limited liability company or any person

or entity that, directly or indirectly, through one or more intermediaries, controls, or is controlled by, or is under common control with, such person.

"CGMP" means Current Good Manufacturing Practices, as defined in a regulation in 21 CFR § 210, 211, or 600 or, as applicable, the applicable European Agency for the Evaluation of Medicinal Products ("EMEA") Guidelines, or any other rules or regulations which may be applicable in any jurisdiction in which Ovamed manufactures the Product pursuant to this Agreement.

"Change Request" means a written request for a change to a Specification.

"Competing Party" means any third party manufacturing, developing, or commercializing a product approved or intended to be approved by a Regulatory Authority for use within the Field of Use which includes the use of TSO.

"Confidential Information" means all information relating to a Party, its business or prospects (including, without limitation, data, know-how, trade secrets, business plans), disclosed by such Party from time to time to the other Party in any manner, whether orally, visually or in tangible form (including, without limitation, documents, devices and computer readable media) and all copies thereof, created by either party.

"Developments" has the meaning given to it in Section 11.1.

"Disclosing Party" has the meaning given to it in Section 12.1.

"FDA" means the United States Food and Drug Administration.

"Field of Use" has the meaning given to it in the Recitals.

"IND Milestone Payments" has the meaning given to it in Section 7.2.

"Intellectual Property Rights" means patents, copyrights, design rights, trademarks, service marks, trade names, trade secrets, know-how, and other intellectual property rights of any kind and nature.

"Late Delivery Credit" has the meaning given to it in Section 3.3.

"<u>Liabilities</u>" means any liability, loss, damage, claim, cost or expense (including reasonable fees of attorneys and other professionals and court costs).

"License" has the meaning given to it in the Recitals.

"Minimum Batch Size" will be mutually agreed to by the parties in writing in the event of changes to the Product pursuant to Article 6 below. There will be no Minimum Batch Size prior to any such entered agreement.

"Ovamed Competitor" means any direct competitor of Ovamed that (i) sells TSO and (ii) sells a product that directly competes with a product sold by Ovamed that constitutes 10% or more of Ovamed's net revenues.

"Ovamed Group" means Ovamed and its Affiliates.

"Products" means initially TSO manufactured in accordance with the Specifications, or as otherwise mutually agreed by the Parties in the event changes are made to the Product pursuant to Article 6 below.

"Purchase Order" means a written purchase order submitted to Ovamed by Collingwood or one of its affiliates under this Agreement for delivery of Products; provided that any terms and conditions contained or incorporated by reference in any such purchase order that conflict with the terms and conditions of this Agreement or the attachments made a part hereof shall be of no force or effect whatsoever concerning the subject matter of this Agreement, and Ovamed's failure to object thereto shall not be deemed a waiver of Ovamed's rights hereunder.

"Receiving Party" has the meaning given to it in Section 12.1.

"Regulatory Approval" means with respect to a nation or multinational jurisdiction any approvals, licenses, registrations or authorizations necessary for the manufacture, marketing and sale of the Product in such nation or jurisdiction.

"Regulatory Authority" means any federal, state or foreign government authority.

"Regulatory Information" means the following information (or the equivalent in any relevant non-United States jurisdiction): IND Safety Reports & Follow-ups (21 CFR) §312.32(c)&(d)), Post-marketing 15-day Alert Reports & Follow-ups (21 CFR §314.80(c)1), Periodic Adverse Drug Experience Reports (21 CFR §314.80(c)2), Field Alert Reports (21 CFR §314.81(b)(1)), Product Complaints (21 CFR §211.198), IND Annual Reports (21 CFR §312.33(b)) and Post-marketing Annual Reports (21 CFR §314.81(b)(2)(i),(iv)&(v)).

"Specifications" means the finished product specifications for the Products and testing standards and procedures to be employed in determining compliance therewith attached hereto as Exhibit A, as amended from time to time in accordance with this Agreement.

"Sublicense" has the meaning given to it in the Recitals.

"Term" has the meaning given to it in Section 8.1.

"Territory" means the entire world, to the extent Ovamed possesses a license to practice the Patent Rights (as defined in the Sublicense) in specific countries and/or territories in the world.

"Transfer Assistance" has the meaning given to it in Section 8.3.

"TSO" means Trichuris suis oya.

"Unit" means approximately 2500 helminth eggs, or such other final dose as approved by the relevant Regulatory Authority, on the basis that a treatment dose will require twenty (20) Units per year and maintenance dose will require ten (10) Units per year.

"Withdrawal Notice Date" has the meaning given to it in Section 8.2.5.

2. MANUFACTURING AND SUPPLY AND PURCHASE.

2.1. Manufacturing.

Case 1:07-cv-03758-JSR

Ovamed agrees to manufacture and supply, and Collingwood agrees to purchase, Product solely for non-clinical, clinical and commercial use in the Field of Use in the Territory, according to the terms of this Agreement. Ovamed also agrees to engage in development with Collingwood in connection with the Products as part of a Change Request pursuant to the terms and conditions as set forth in Section 6.1.1 of this Agreement.

2.2. Manufacturing Facilities.

In addition to the existing manufacturing facility in Germany, Ovamed shall establish at least two (2) more manufacturing facilities located in the United States, which will be in compliance with CGMP and the first of which will be completed and operational upon the completion of the first clinical phase III approval process with the FDA. Ovamed will establish a second manufacturing facility located in the United States, which will be completed and operational prior to the first anniversary of the first commercial sale of the Products. Upon the establishment of the United States manufacturing facilities and any others, and on each twelvemonth anniversary thereof, Ovamed will provide to Collingwood written certification that all manufacturing facilities in the United States at which Product is manufactured are in compliance with CGMP and that all manufacturing facilities existing outside of the United States at which Product is manufactured are in compliance with the relevant regulations of such jurisdiction.

2.3. Third Party Manufacturers.

Ovamed shall remain responsible for its obligations under this agreement notwithstanding any delegation hereunder.

2.4. Purchase Orders.

All orders placed by Collingwood for the Products require a Purchase Order. Collingwood shall submit to Ovamed a 12 month rolling supply forecast in writing and a firm Purchase Order for the purchase of any Products at least 90 days prior to the specified delivery date in writing, and Ovamed shall accept such Purchase Order in writing, subject to the adherence of such Purchase Order to the terms and conditions of this Agreement. Each Purchase Order shall be signed by an employee of Collingwood and specify the quantity of Products ordered, the purchase price, the requested delivery date or dates, and delivery locations. Ovamed reserves the right to cancel, suspend, refuse or delay any orders if Collingwood fails to make any payment when due, and such failure continues after sixty (60) days notice of such non-payment

from Ovamed. At the reasonable request of Ovamed, Collingwood will cooperate and submit to Ovamed any information required for Ovamed to obtain "accounts receivable insurance" from a bona fide third party carrier (such information will be restricted to information that is customarily required for such types of insurance).

2.5. <u>Inspection and Notifications.</u>

- 2.5.1. <u>Inspections</u>. During regular business hours and upon reasonable advance notice, Ovamed shall permit, and upon reasonable notice and coordination of schedules shall use reasonable efforts to cause each of its Approved Subcontractors to permit, Collingwood, its consultants and/or contractors reasonably acceptable to Ovamed (or if not reasonably acceptable to Ovamed, Ovamed will supply a list of appropriately qualified consultants acceptable to it for Collingwood to use) and government personnel (including without limitation personnel from the FDA, for whom advance notice is not required, or any other Regulatory Authority in the Territory) to inspect the facilities of Ovamed and each of its Approved Subcontractors and to review manufacturing activities related to the Products solely to the extent necessary for, and for the purpose of assessing Ovamed's regulatory and quality compliance with, CGMP and for the purpose of determining compliance with the Specifications; provided that, (i) Collingwood shall not be permitted to exercise its right of inspection under this Section more than four times in any twelve month period (ii) such restriction on the number of inspections shall not apply to governmental inspections, (iii) each party conducting an inspection, other than governmental, shall execute with Ovamed a nondisclosure agreement containing a conventional penalty in case of breach not less than € 500. 000, reasonably acceptable to Ovamed with regard to all materials inspected. Ovamed shall permit, and use reasonable efforts, to cause each of its Approved Subcontractors to permit, Collingwood and government personnel, to review and make copies of all relevant documents related to the Products that might reasonably be requested for such purposes. The costs of Ovamed's reasonable expenses incurred in connection with such inspections, shall be borne by Collingwood.
- 2.5.2. Notification. Ovamed shall promptly provide Collingwood notice of all inspections of Ovamed's facilities by any Regulatory Authority reasonably related to Ovamed's performance hereunder or the subject matter of this Agreement, and each Party shall promptly provide the other Party with notice of all (A) written claims and allegations, and (B) claims and allegations made orally that reasonably appear to warrant investigation or response, in either case of which Ovamed or Collingwood is aware, that Ovamed is not complying with CGMP or with the relevant Specifications. The obligations of this Section apply equally to any such notices provided to Ovamed's Approved Subcontractors to Ovamed's knowledge.
- 2.5.3. Records. Ovamed shall maintain all of its manufacturing and analytical records, all records of shipments of Products and all reasonable validation data relating to Products for a minimum of five (5) years from Product

shipment. Collingwood shall maintain all of its sales and analytical records, all records of shipments of Products and all reasonable validation data relating to Products for a minimum of two (2) years from Product shipment. Each Party agrees that, in response to any complaint, or in the defense by the other Party of any litigation, hearing, regulatory proceeding or investigation relating to any Products, it shall make available to the other Party, at the other Party's cost and expense, such employees and records reasonably necessary to permit the effective response to, defense of, or investigation of such matters, subject to appropriate confidentiality protections and such records shall be deemed Confidential Information of the disclosing party hereunder.

Document 1-5

2.6. Semi-Annual Relationship Review.

The Parties will meet or speak by telephone during the last month of each semi-annual period following the Effective Date and at such other times as mutually agreed upon by the parties, to review their relationship and performance under this Agreement, including but not limited to, review of the Specifications. This review will not give rise to any amendment to the Agreement other than pursuant to Section 13.8 hereunder.

2.7. Documentation. Ovamed will supply all reasonable documentation related to the Products to support Collingwood's effort to obtain and maintain Regulatory Approval for the Sale of Products that is required to comply with guidance documents and regulations of Regulatory Authorities that is relevant to biological agents for human use (the "Documentation"). To the extent that the Documentation required to be supplied by Ovamed under this Section is documentation, or is substantially the same as documentation, that Ovamed has, at the time, in its possession, then Ovamed shall supply such Documentation without any additional charge to Collingwood; otherwise, Collingwood shall pay to Ovamed an amount equal to Ovamed's fully burdened costs, including, but not limited to, overhead, incurred in performing the work required to prepare such Documentation.

3. DELIVERY, ACCEPTANCE, REJECTIONS.

3.1. Delivery.

3.1.1. Delivery. Ovamed shall deliver all Products ordered under this Agreement corresponding to the quantities, delivery dates and delivery locations set forth in each Purchase Order provided to Ovamed pursuant to and in accordance with Section 2.3. All Products shipped pursuant to the terms of this Agreement shall be manufactured not more than three (3) months preceding the shipment date, labeled and packed for shipment in accordance with the Specifications set forth on Exhibit A, and shall be marked for shipment to the designated location specified in the Purchase Order. All deliveries of Products will be to the designated location specified in the Purchase Order. Ovamed will have no further responsibility for Products after, and all risk of damage to or loss or delay of Products will pass to Collingwood upon, delivery by Ovamed to the designated carrier.. The prices of the Products include all palletizing, packing,

crating and storage charges at Ovamed facility, other than as set forth in Section 3.1.2 below. Collingwood will pay for all freight, insurance and other shipping expenses incurred during shipment to the designated location and Ovamed shall be responsible for clearing the Product for import, export and for other customs matters. Both parties (Ovamed and Collingwood) shall consult with each other in advance of each shipment and shall cooperate with each other to permit Ovamed to make suitable shipping, insurance, customs and related arrangements. Ovamed shall obtain all appropriate approvals and consents of any governmental authority in the United States or other relevant jurisdictions, as applicable, necessary for the manufacture (including packaging), and exportation from the place of manufacture of the Products to Collingwood and Ovamed shall comply with all applicable laws and regulations pertaining thereto.

3.1.2. Except to the extent resulting from Ovamed's failure to comply with its obligations under this Agreement, Collingwood will bear the actual and reasonable costs (including storage) resulting from Collingwood's failure to receive Products at scheduled times.

3.2. Acceptance and Rejection.

3.2.1. Acceptance. Ovamed will provide Collingwood with a certificate of analysis for each invoiced Product substantially in the form of Exhibit D. Each shipment of Product will be deemed accepted by 5:00 p.m. EST on the (fifth) 5th day after receipt by Collingwood unless Collingwood notifies Ovamed prior to such time that the shipment (i) contains any discrepancy between the actual quantity of Product supplied and the quantity of Product quoted in the supply documents delivered with the applicable Products, (ii) is incorrectly invoiced, or (iii) does not contain a certificate of analysis showing conformity of the Product with the Specifications. The shipment will be deemed rejected upon delivery of such notice by Collingwood; provided, however, if the original shipment of the Product is found to be conforming, then Collingwood shall pay to Oyamed any due amount plus interest in the amount of 8% per year of the unpaid amount. Each shipment of Product(s) accepted by Collingwood under this Agreement will be subject to inspection and performance testing by Collingwood within a period of forty-five (45) days after receipt of a particular shipment of Product(s) (as applicable, the "Inspection Period") to determine whether the Product(s) in such shipment complied at the time of delivery to the carrier at Ovamed's facilities with the Specifications and any applicable warranties under this Agreement. Collingwood shall promptly, but in no event more than five (5) business days after the Inspection Period (the "Notice Period"), notify Ovamed if any particular shipment did not so comply with the Specifications or applicable warranties at the time of delivery to the carrier. Upon request by Collingwood, during the Inspection Period, Ovamed will promptly provide copies of completed batch records (including deviations and corrective actions), and Collingwood shall pay for the actual costs of copying and sending such batch records on a cost basis. If Collingwood and Ovamed reasonably determine that the Product(s) did not

comply with the Specifications or the applicable warranties under this Agreement at the time of delivery to the carrier, Collingwood shall promptly notify Ovamed of such non-compliance, but in no event more than the later of (x) five (5) days after Collingwood's receipt of all such completed batch records or (y) the expiration of the Notice Period. If the Parties are unable to agree on whether such non-compliance has occurred within ten (10) days, then the Parties shall promptly engage a third party testing laboratory, mutually agreed upon and that shall enter into a confidentiality Agreement with Ovamed and Collingwood, to determine whether such non-compliance has occurred prior to the delivery of Product(s) to the carrier. The costs of such third party testing laboratory shall be borne by Collingwood, unless such third party testing laboratory determines that the particular shipment of Product was non-compliant at Ovamed's facilities at the time of delivery to the carrier, in which case such costs shall be borne by Ovamed. If Collingwood does not deliver written notice to Ovamed during the Notice Period that Collingwood rejects such shipment because of a noncompliance at the time of delivery to the carrier at Ovamed's facilities, Collingwood will be deemed to have accepted the shipment, subject to any right it may have under law or this Agreement.

3.2.2. Replacement; Expenses. If a Product shipment is rejected by Collingwood under Section 3.2.1(iii) or because such shipment did not comply at the time of delivery to the carrier with the Specifications and any applicable warranties under this Agreement as set forth in Section 3.2.1 above (subject to the dispute resolution procedure set forth therein), then Collingwood may, at its discretion, either (i) obtain a credit or refund, in Ovamed's sole discretion, for the amount paid by Collingwood for the non-conforming Product or (ii) require Ovamed to correct or replace, in Ovamed's sole discretion, the non-conforming Product so that it complies. If Collingwood requests, Oyamed agrees to correct or replace any such Product as soon as is practicable but no later than 60 days after Collingwood's request for such correction, and will bear all reasonable expenses of making such corrections. If Ovamed is unable to so correct or replace the Product within such 60 day period, it will so notify Collingwood no later than two (2) days after the end of such 60 day period, whereupon Collingwood will have the option, at its sole discretion, to (x) require Ovamed to credit Collingwood for the amount paid by Collingwood for such Product or (y) require Ovamed to use all commercially reasonable efforts to promptly replace the Product at Oyamed's expense. Upon Ovamed's request and at Ovamed's expense Collingwood shall return or dispose of the non-conforming Products. Without limiting the foregoing, Ovamed will reimburse or credit Collingwood for any costs or expenses paid by Collingwood at the instructions of Ovamed or as required by relevant regulations related to the return, repair or destruction of the nonconforming Product(s). Notwithstanding the foregoing, if the original shipment of Product is found to be conforming, then Collingwood shall pay for the replacement shipment in accordance with the terms of this Agreement plus interest as applicable to late payment. Any credit or refund due under this Section will bear interest, which shall accrue at an annual percentage rate equal to the

Filed 05/11/2007

lesser of one percent (1.0%) per month or the maximum rate allowable by law at the date of such credit or refund is due until such refund is paid or such credit is used.

3.3. <u>Late Delivery Credit</u>.

3.3.1. Credit. Subject to a Force Majeure Event, if Ovamed fails to deliver any Products within ten (10) days after the delivery date specified in an accepted Purchase Order to the designated location specified in the Purchase Order, Ovamed will give Collingwood a credit to be applied to the purchase price owed for such Product(s) (a "Late Delivery Credit"); provided, that (a) such credit shall be applied to future payments due by Collingwood under this Agreement, if any; and (b) except as set forth in Section 8.2.1 and 8.2.2, such Late Delivery Credit shall be Collingwood's sole and exclusive remedy for any such delay. The amount of the Late Delivery Credit will vary based on the number of days a delivery follows the date specified in the accepted Purchase Order, and will equal the following percentage of the purchase price for the Product(s) that is delivered late:

Number of Days Late	Late Delivery Credit
11-21	5% of the purchase price for late Product
22-30	10% of the purchase price for late Product
>30	15% of the purchase price for late Product

Collingwood may apply the Late Delivery Credit to reduce the amount due to Ovamed under the invoice for late-delivered Product. In the event that Ovamed knows that any Product being shipped to Collingwood will be delivered more than ten days after the delivery date specified in the accepted Purchase Order for such Product due to reasons that are within Ovamed's control, Ovamed will note the Late Delivery Credit that applies to that Purchase Order in the invoice for that Purchase Order.

4. RECALLS, ADVERSE EVENT REPORTING, COMPLAINTS; REGULATORY.

4.1. Recalls.

4.1.1. Recalls of Product. Collingwood shall promptly notify Ovamed of any recall, product withdrawal, or field correction to the Product, and provide copies of all press releases related to such action, whether or not effected voluntarily or requested or ordered by any federal or state agency or government agency. Ovamed may recommend a recall, product withdrawal or field correction, however, subject to Ovamed's obligation to adhere to all applicable laws and regulations, the decision to conduct such an activity shall be Collingwood's alone. Ovamed shall reasonably cooperate with Collingwood as necessary to effectuate any such recall, withdrawal or correction, at Collingwood's sole cost and expense. Subject to applicable law, regulation or

Regulatory Authority request, Collingwood or its designee shall make all contacts with the FDA and any other regulatory agencies, shall be responsible for coordinating all of the necessary activities in connection with such recall, product withdrawal, or field correction and shall make any statements to the media, including, but not limited to, press releases and interviews for publication or broadcast related to such recall, product withdrawal, or field correction; provided that, Collingwood will provide Ovamed written notice concurrently or as soon as practicable after Collingwood makes any statement to the FDA, regulatory agency, media and/or to the public related to a recall, product withdrawal, or field correction that specifically refers to Ovamed or is reasonably related to any of the Products, which sets forth such statement. Ovamed will reasonably cooperate with Collingwood in the conduct of such activities. Collingwood shall keep Ovamed fully informed of progress and shall consult with Ovamed in relation to all material decisions or actions as may reasonably relate to a recall, product withdrawal, or field correction of the Products.

4.1.2. Recall Expense. Ovamed shall bear the full expense of both Parties incurred in any recall, withdrawal or correction of the Product resulting from (i) failure of any Product to meet the Specifications at the time of delivery of such Product by Ovamed to the carrier, or (ii) Ovamed's failure to manufacture any Product in accordance with CGMP and all other applicable laws, and Collingwood shall bear the full expense of both Parties incurred in any other recall, withdrawal or correction of the Product. Any dispute between the Parties as to which Party is responsible for a defect will be made by an independent arbitrator, mutually satisfactory to the Parties, and having sufficient scientific and manufacturing skills necessary to adjudicate upon the matter in dispute. The costs of such arbitrator will be borne by the Party against whom the arbitrator rules. Such expenses of recall shall include, without limitation, the expenses of notification and destruction or return of the recalled Product and the sum paid by a third party for the recalled Product. In the event, however, that a recall is partially caused by reasons as set forth in subsections (i) and/or (ii) of this Section 4.1.2 and partially for other reasons, then each Party shall be responsible for its proportionate share of the recall expenses based on its proportionate share of causation.

4.2. Adverse Experience Reporting.

Each Party shall cooperate with the other Party and provide all assistance reasonably requested by the other Party for the other Party to respond in a timely fashion to Regulatory Authorities in the event of product complaints, Field Alert Reports, SUSARs, or Adverse Event reports which require submission to Regulatory Authorities as expedited reports, e.g., 15-day Alert Reports or in other regulatory submissions including but not limited to IND Annual Reports and NDA/BLA Annual Reports or Periodic Safety User reports, each as defined by the applicable Section of the U.S. Code of Federal Regulations, in accordance with current FDA and any other applicable guidance and regulations, including without limitation providing to the other Party all Regulatory Information in its possession reasonably required for FDA

compliance. Each Party may use such information to meet its respective legal and regulatory obligations. The capitalized terms used in this Section but not defined in this Agreement shall have the customary meaning under current FDA and European Union guidance and regulations.

4.3. Complaints.

Unless otherwise required by law, Collingwood shall have sole responsibility and authority to respond to any customer or other complaints with respect to the Products or other aspects of the Product; provided, however, Collingwood will provide Ovamed written notice concurrently with or as soon as practicable after Collingwood makes any statement to such complaining party, the FDA, regulatory agency, media and/or to the public in response to any complaint that may be reasonably related to the Products that specifically refers to Oyamed or any of the Products, which sets forth such statement. Except as otherwise provided herein, Ovamed will not be liable or made responsible for any act or cost incurred or committed by Collingwood in connection with any action taken by Collingwood under this Section. Each Party shall promptly advise the other Party of all relevant details if it receives any complaints pertaining to the Product. Collingwood shall promptly advise Ovamed of all relevant details if it receives any significant complaints pertaining to the Product (except that any complaints pertaining to the Product that require a report to a Regulatory Authority shall be deemed to be significant), and Ovamed shall promptly advise Collingwood of all relevant details if it receives any significant complaints pertaining to the Product (except that any complaints pertaining to the Product that require a report to a Regulatory Authority shall be deemed to be significant). Subject to the foregoing, Ovamed shall provide reasonable cooperation and assistance to Collingwood in responding to complaints with respect to the Products.

4.4. Regulatory Approvals.

The Parties shall fully cooperate in good faith, and shall provide all reasonable assistance and information, in a timely manner, to each other, to obtain and maintain all Regulatory Approvals that are required to manufacture, distribute, use or sell the Products, including without limitation the preparation, filing and maintenance of any U.S. Biological License Application or European Marketing Authorization (or equivalent in other jurisdictions). If there are incremental regulatory filing fees that are applicable to the Products, Collingwood will bear such regulatory fees. The parties shall also reasonably assist each other in responding to requests and inquiries from applicable Regulatory Authorities prior to, during and after regulatory review periods, including without limitation, providing all data, records and reports required in order to comply with the regulatory Authority request.

5. QUALITY AND CAPACITY.

5.1. Ovamed Representations, Warranties and Covenants.

Ovamed hereby represents, warrants and covenants to Collingwood that the Products at the time of delivery to Collingwood at the designated location: (a) shall be manufactured in compliance with CGMP and all other applicable regulatory and governmental regulations, as applicable; (b) shall conform to the certificates of analysis supplied with each shipment pursuant to Section 5.2; and (c) shall be free and clear of any lien or encumbrance and Ovamed will have

all rights necessary to transfer title to the Products to Collingwood. The foregoing warranty shall not apply to the extent that the Product has been subject to use or other conditions not in accordance with the applicable Specifications, or has otherwise been the subject of mishandling, misuse, neglect, alteration or damage by the carrier or Collingwood.

5.2. Testing of Product for Conformance with Specifications.

Ovamed will test each batch of the Products supplied to Collingwood under this Agreement and provide Collingwood with a written certificate of analysis (in the form set forth in Exhibit D) along with each batch of Products that confirms that such Product meets the Specifications and warranties under this Agreement. Collingwood may retest each batch of Products and perform other performance measurements in accordance with Section 3.2.1 of this Agreement to confirm that such batch meets the applicable Specifications and warranties in accordance with this Agreement.

6. CHANGES IN SPECIFICATIONS OR MANUFACTURING PROCEDURES.

6.1. Sponsored Changes.

- 6.1.1. Changes Sponsored by Collingwood. Collingwood shall notify Ovamed in writing of a Change Request proposed by Collingwood no less than 180 days prior to the proposed effective date for the Change Request. The notification shall include a description of the proposed changes, information regarding medical, clinical, and regulatory factors and the proposed implementation date. Notification shall also include the reasonably appropriate documentation to support Ovamed's investigation of the impact of this proposal. Ovamed may review the feasibility of the implementation and any other aspect of the proposed Change Request. Ovamed shall use commercially reasonable efforts to advise Collingwood of its decision with respect to the proposed Change Request as soon as practicable but in any case no later than within 120 days after receipt of Collingwood's written notification. No Change Request shall be made by Collingwood without Ovamed's prior written approval, which approval may be provided or withheld in Ovamed's reasonable discretion. Until a Change Request has been agreed to in writing by both Parties, the Change Request shall not be effective, and the Parties shall continue to perform their obligations under the then-effective Specifications. Any change that is in connection with the Minimum Batch Size and in connection with a mandatory change resulting from a Regulatory Authority communication, shall not be considered a Change Request sponsored by Collingwood.
- 6.1.2. Changes Sponsored by Ovamed. Ovamed shall notify Collingwood in writing of a Change Request proposed by Ovamed no less than 180 days prior to the proposed effective date for the Change Request. If so proposed, Ovamed will provide Collingwood with samples of Product that incorporates or is a result of the Change Request. The notification shall include a description of the proposed changes, information regarding medical, clinical, and regulatory factors and the proposed implementation date. Notification shall also

Filed 05/11/2007

include the reasonably appropriate documentation to support Collingwood's investigation of the impact of this proposal. Collingwood may review the feasibility of the implementation and any other aspect of the proposed Change Request. Collingwood shall use commercially reasonable efforts to advise Ovamed of its decision with respect to the proposed Change Request as soon as practicable but in any case no later than within 120 days after receipt of Ovamed's written notification. No Change Request shall be made by Ovamed without Collingwood's prior written approval, which approval may be provided or withheld in Collingwood's reasonable discretion. Until a Change Request has been agreed to in writing, the Change Request shall not be effective, and the Parties shall continue to perform their obligations under the then-effective Specifications. Any change that is in connection with the Minimum Batch Size and in connection with a mandatory change resulting from a Regulatory Authority communication, shall not be considered a Change Request sponsored by Ovamed.

6.1.3. FDA Agreement. To the extent that a Change Request accepted or proposed by Collingwood will require any filing with any Regulatory Authority or the granting of any Regulatory Approval for the Product, each Party shall reasonably cooperate with each other and take all reasonable actions and provide all information as may be reasonably requested by Collingwood or Ovamed in connection with preparing such filings and obtaining such Regulatory Approval. Costs incurred by Ovamed in connection with the above will be subject to the terms of Sections 6.1.1 and 6.1.2 above. Without limiting any other provision of this Article 6, Ovamed will not change any aspect of the Product or the process by which the Product is manufactured that requires the FDA approval if the FDA does not provide written confirmation, prior to making the change, that the change will not terminate or otherwise impair any Regulatory Approval for the Product. Collingwood will support and assist Ovamed in any communications with the FDA that may be required as described above in order to achieve such FDA confirmation.

6.2. Impact on Inventory.

Any agreed modification following a Change Request shall only take effect once all Product manufactured pursuant to the previous Specifications and already scheduled for delivery has been delivered under the terms of this Agreement.

7. PAYMENT.

7.1. Price.

In consideration of Ovamed's manufacture and supply of Products hereunder. Collingwood shall pay to Ovamed an amount equal to the total number of Units delivered in each calendar quarter (the "Actual Amount") multiplied by the corresponding Price (per Unit), as defined in the following sentence, minus any Late Delivery Credit owed to Collingwood under Section 3.3 of this Agreement ("the Interim Amount"). On the Effective Date of this Agreement, the "Price" shall be \$125 per Unit for clinical supplies and \$175 per Unit for commercial

supplies. During the Term, Ovamed will use commercially reasonable efforts to decrease the cost of goods sold to Collingwood (as determined in accordance with generally accepted accounting principles, consistently applied). Ovamed will promptly notify Collingwood of any such decreases and the Price shall be decreased by 50% of any such decrease in cost of goods sold. In case the FDA or other official Regulatory Authority mandates that more than 20 Units to be dosed to the patient Collingwood shall not be required to pay an amount greater than: (i) Three Thousand Five Hundred Dollars (\$3500) per patient per year for total commercial supplies of Units in the first year in which Units are administered to a patient; and (ii) One Thousand Seven Hundred Fifty Dollars (\$1750) per patient per year for total commercial supplies of Units in any subsequent year following the first year in which Units are administered to a patient.

7.2. Milestone Credit.

So long as Collingwood makes the milestone payments to Ovamed which are set forth in Sections 4.3.1 and 4.3.2 of the Sublicense (the "IND Milestone Payments"), Ovamed will give Collingwood a credit, said credit not to exceed Three Million Dollars (\$3,000,000), to be applied to the purchase price owed for any Units purchased for clinical supplies of Products up to the aggregate amount of the IND Milestone Payments. To the extent that the aggregate amount of IND Milestone Payments exceeds the aggregate purchase price of clinical supplies, any excess will be applied as a credit against the purchase price of any commercial supplies of Products.

7.3. Payment.

Ovamed will invoice Collingwood for Products upon delivery. Amounts owed under invoices shall be due and payable in U.S. currency within 30 days after date of such invoice, subject to the offset described in Section 7.1. A late payment charge calculated from the date such payment was due at the prime rate of interest as reported in The Wall Street Journal on the day the payment was due or the highest interest rate allowed by applicable law shall be charged upon all unpaid amounts due hereunder. All payments due hereunder shall be made by wire transfer from a bank in the United States in immediately available funds to a bank designated by Ovamed, or such other bank upon prior written notice.

7.3. Overdue Amounts; Disputes.

Subject to Section 3.2.1, in the event that Paramount disputes in good faith any amount that Ovamed claims to be due under this Agreement Paramount may so notify Ovamed at the time such payment is made, and if any disputed amount is ultimately determined to not be due hereunder Ovamed will refund promptly such amount to Paramount plus interest, calculated from the date such payment was due at the prime rate of interest as reported in the The Wall Street Journal on the day the payment was due or the highest rate allowable by law at the date of such decision.

8. TERM AND TERMINATION.

8.1. Term.

Unless terminated in accordance with Section 8.2, the term (the "Term") of this Agreement shall commence on the Effective Date and shall continue until the fifth anniversary of the Effective Date, unless earlier terminated pursuant to the terms of this Agreement, provided that Collingwood may extend the Term for successive one (1) year periods by providing written notice of such extension to Ovamed not later than 12 months prior to the then expiration date of the Term.

8.2. Termination.

- 8.2.1. Termination for Cause. Either Party may terminate this Agreement immediately without penalty or further obligation to the other, upon written notice to the other Party if (i) the other Party makes a general assignment for the benefit of creditors, or a receiver or similar officer is appointed to take charge of all or substantially all of the other Party's assets; (ii) the other Party ceases to carry on its business; (iii) a bankruptcy or similar petition is filed by the other Party or a final insolvency order is issued against the other Party, and in the case of an involuntary petition, the proceeding is not dismissed within 120 days; or (iv) the other Party is in material breach of any material representation, warranty, covenant or obligation under this Agreement, and such breach is not cured within 60 days of receiving written notice thereof. Without limiting the foregoing, Collingwood shall have the right to terminate this Agreement as provided in any of Sections 8.2.2 through 8.2.6. The Parties agree that a "material breach of a material obligation" includes but is not limited to any failure by Ovamed to deliver (x) at least 50% of the amount of Product in any particular order pursuant to Section 3.1 within 60 days of the required delivery date, (y) 75% of the amount of Product in any particular order pursuant to Section 3.1 within 90 days of the required delivery date or (z) certification reasonably satisfactory to Collingwood pursuant to Section 2.2.
- 8.2.2. Failure to Supply. The parties will agree about the quantity to be delivered in forecasts that will be determined by the parties each year. In the event that Ovamed fails (i) to satisfactorily supply at least 50% of the amount of Product in any particular order within 90 days of the required delivery date or at least 75% of the amount of Product in any particular order within 270 days of the required delivery date, (ii) to substantially perform its obligations in connection with United States or other relevant Regulatory Approval of the Products and such failure has continued for more than thirty (30) days, or such longer period as reasonably necessary to cure such failure or such period required by the relevant Regulatory Approval authority, or (iii) to have adequate operational manufacturing facilities such that it is unable to manufacture Product, or unable to manufacture product in accordance with Specifications, for a period of sixty (60) days or more [(i), (ii) and (iii) individually or collectively referred to herein as the "Manufacturing Failure"], and (x) Ovamed does not, at the time, have the right to terminate this Agreement under Section 8.2.1 and (y) Collingwood has not, at the time, developed a commercial second source (on commercially reasonable terms) for a product that can be substituted for the Product and that can meet the supply

shortage resulting from Ovamed's failure to supply, then, upon notice of such failure from Collingwood, Collingwood may terminate this Agreement and receive a worldwide, royalty-free, perpetual, non-transferable (except as set forth in Section 13.3 below), non-exclusive, fully paid license, with the right to grant sublicenses for the sole purpose of manufacturing the Product on behalf of Collingwood (provided each such sublicensee signs a confidentiality agreement with Ovamed on terms consistent with the confidentiality obligations under this Agreement), under all intellectual property owned by Ovamed or for which Ovamed has the right to grant a license or sublicense pursuant to this Section and which is reasonably necessary or useful to manufacture and sell the Product in the Field of Use (the "Manufacturing IP") (collectively, the "Manufacturing Failure License"), and such license shall be effective immediately upon notice of such election by Collingwood, and (b) Ovamed shall provide all assistance reasonably requested by Collingwood to assist Collingwood or a third party acting on behalf of Collingwood in the manufacturing of the Product in accordance with the Specifications, provided however, that Collingwood shall reimburse Ovamed for any reasonable expenses it incurs in relation to its rendering of such assistance; Notwithstanding anything to the contrary herein, if Ovamed delivers to Collingwood a remediation plan reasonably acceptable according to which full remediation of any Manufacturing Failure will be achieved within nine (9)months from the first date of such Manufacturing Failure, then this Agreement shall remain in effect, provided however, that Collingwood shall have the right to use and have used all Manufacturing IP to manufacture or have manufactured Product during such period that Ovamed is engaged in such remediation. Such plan shall be delivered to Collingwood within 30 days after the failure occurred. Collingwood may terminate this Agreement immediately, without penalty or further obligation to Ovamed, if Ovamed fails to achieve remediation within such (nine) 9-month period and Collingwood shall immediately be entitled to the Manufacturing Failure License.

- 8.2.3. Failure to Obtain Regulatory Approval for the Product.

 Collingwood may terminate this Agreement immediately, without penalty or further obligation to Ovamed, if Collingwood fails to obtain Regulatory Approval for the Product in the United States, provided that Collingwood will be obligated to: (i) purchase such quantity of Products that is already scheduled for delivery in the three (3) month period following the date Collingwood notifies Ovamed of such withdrawal requirement ("Withdrawal Notice Date"), and (ii) pay for costs actually incurred by Ovamed, as of the date of termination pursuant to this Section, in performing the work required under an Collingwood sponsored Change Request.
- 8.2.4. <u>Early Failure in Clinical Trials</u>. Collingwood may terminate this Agreement immediately, without penalty or further obligation to Ovamed, if the Product fails (i) preclinical pharmacology and toxicology studies or (ii) any clinical trial (or the results from a clinical trial are such that, in Collingwood's good faith judgment, it would not be commercially reasonable to continue

- 8.2.5. Withdrawal from US or Other Market. In the event FDA or any other Regulatory Authority requires that the Product be withdrawn from the applicable market, or in the event that Collingwood at any time determines that it is not, or will not be, commercially feasible to market the Product in the United States or other relevant market, then Collingwood shall have the right, on each such occurrence, to terminate this Agreement immediately, without penalty or further obligation to Ovamed, provided however, that if such withdrawal arises as a result of a component other than the Product, Collingwood will be obligated to: (i) purchase such quantity of Products that is already scheduled for delivery in the three (3) month period following the date Collingwood notifies Ovamed of such withdrawal requirement ("Withdrawal Notice Date"), and (ii) pay for costs actually incurred by Ovamed, as of the date of termination pursuant to this Section, in performing the work required under an Collingwood sponsored Change Request.
- 8.2.6. <u>Termination of Sublicense</u>. This Agreement will terminate immediately upon the termination of the Sublicense.

8.3. Survival.

The Parties agree that any provisions which by their nature should survive termination or expiration of this Agreement to give effect to their intent, shall survive, including without limitation, Articles 4 (Recalls, Adverse Event Reporting, Complaints), 7 (Payment), 9 (Indemnification and Insurance), 10 (Liability), 11 (Intellectual Property), 12 (Confidential Information), and Sections 8.4 (Survival), 13.1 (Correspondence and Notices), 13.5 (Use of Name), 13.9 (Waiver), 13.10 (Severability), 13.12 (Governing Law), and 13.13 (Jurisdiction; Venue; Service of Process).

9. INDEMNIFICATION AND INSURANCE.

9.1. Ovamed Indemnification of Collingwood.

Ovamed will defend, indemnify, and hold Collingwood, its officers, directors, employees, and agents (each an "Indemnified Party") harmless against any and all third party Liabilities to the extent arising from (i) any asserted infringement or other violation of any third party Intellectual Property Rights arising from Ovamed's manufacture or supply to Collingwood of the Products under this Agreement; or (ii) any third party claim arising from personal injury caused by a defect in the manufacture or workmanship of the Product (including claims arising from the Products not meeting the Specifications at the time of delivery).

9.2. Collingwood Indemnification of Ovamed.

Collingwood will defend, indemnify, and hold Ovamed, its officers, directors, employees, and agents harmless (each an "Indemnified Party") against any and all third party Liabilities to the extent arising from (i) any third party claim against Ovamed asserting infringement or other violation of any third party Intellectual Property Rights arising from the Product (but only to the extent the claim does not arise from the manufacture, use or sale of the Products); or (ii) any third party claim arising from a personal injury caused by a defect in the Product (but only to the extent the claim does not arise from the Products not meeting the Specifications at the time of delivery).

9.3. Procedure.

Each Party will promptly notify the other Party in writing in the event it becomes aware of a claim for which indemnification may be sought hereunder. In case any proceeding (including any governmental investigation) shall be instituted involving any Party in respect of which indemnity may be sought pursuant to this Article 9, such Party will promptly notify the other Party (the "Indemnifying Party") in writing. The Indemnifying Party shall have sole control of any such claim. The Indemnified Party will reasonably cooperate with the Indemnifying Party in defense of such matter. In any such proceeding, the Indemnified Party will have the right to retain its own counsel, but the fees and expenses of such counsel shall be at the expense of the Indemnified Party. The Indemnifying Party shall not be liable for any settlement of any proceeding effected without its written consent, but, if settled with such consent or if there be a final judgment for the plaintiff, the Indemnifying Party agrees to pay any such settlement or final judgment. The Indemnifying Party shall not, without the written consent of the Indemnified Party, effect any settlement of any pending or threatened proceeding in respect of which the Indemnified Party is, or arising out of the same set of facts could have been, a party and indemnity could have been sought hereunder by the Indemnified Party, unless such settlement includes a release of the Indemnified Party from all liability on claims that are the subject matter of such proceeding.

9.4. Insurance.

Ovamed agrees to maintain during the Term and for three (3) years thereafter, at its own expense, insurance from a reputable and financially secure insurance company, providing \$3 million of protection per any one occurrence and for the insurance period against Ovamed's legal liability deriving from claims, suits, losses and damages arising out of alleged defects in the Products. Collingwood will be named as an additional insured under such policy and Ovamed will provide, at Collingwood's request, a certificate of insurance evidencing its obligations hereunder. Such certificate shall provide Collingwood with thirty (30) days written notice of cancellation, modification or termination of such insurance. All such insurance policies will provide a worldwide coverage territory including suits brought within the United States, its territories and possessions.

Collingwood agrees to maintain during the Term and for three (3) years thereafter, at its own expense, insurance from a reputable and financially secure insurance company, providing at least \$3 million of protection per any one occurrence and for the insurance period against Collingwood's legal liability deriving from claims, suits, losses and damages arising out of alleged defects in the Product. Ovamed will be named as an additional insured under such policy

and Collingwood will provide, at Ovamed's request, a certificate of insurance evidencing its obligations hereunder. Such certificate shall provide Ovamed with thirty (30) days written notice of cancellation, modification or termination of such insurance. All such insurance policies will provide a worldwide coverage territory including suits brought within the United States, its territories and possessions.

Each Party hereby waives any claims against the other (whether founded upon the indemnification provisions contained in this Agreement or otherwise) to the extent any such claim is covered by such waiving Party's insurance carrier, and loss proceeds are paid to and received by such waiving Party, and provided such waiver (i) is not in violation of the policies of insurance under which such loss proceeds are so paid; (ii) does not invalidate such insurance and (iii) does not disproportionately increase the premiums thereof.

10. LIABILITY.

IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER FOR ANY INCIDENTAL, CONSEQUENTIAL, SPECIAL OR PUNITIVE DAMAGES OF ANY KIND OR NATURE ARISING OUT OF THIS AGREEMENT, WHETHER SUCH LIABILITY IS ASSERTED ON THE BASIS OF CONTRACT, TORT (INCLUDING THE POSSIBILITY OF NEGLIGENCE OR STRICT LIABILITY), OR OTHERWISE, EVEN IF THE PARTY HAS BEEN WARNED OF THE POSSIBILITY OF ANY SUCH LOSS OR DAMAGE, AND EVEN IF ANY OF THE LIMITED REMEDIES IN THIS AGREEMENT FAIL OF THEIR ESSENTIAL PURPOSE.

11. INTELLECTUAL PROPERTY.

- 11.1. Ownership of Intellectual Property. All Intellectual Property Rights developed or conceived by either party in connection with this Agreement ("Developments") shall be owned by the party who invented such Development (where inventorship is defined based on concept of inventorship set forth by the patent laws of the United States). Ovamed has the worldwide, fully paid, perpetual exclusive right to fully exploit such Developments as required to perform its obligations under this Agreement. As long as Collingwood purchases products - fully paid - from Ovamed under this agreement, Collingwood has the worldwide, fully paid, perpetual license to fully utilize any Developments owned by Ovamed. Collingwood agrees to reasonably cooperate when requested by Ovamed, at Ovamed's expense, in enforcing Ovamed's Intellectual Property Rights embodied in the Developments, including without limitation prosecuting and maintaining patent applications and patents and being joined as a party to an action brought by Ovamed to enforce such rights. Ovamed agrees to reasonably cooperate when requested by Collingwood, at Collingwood's expense, in enforcing Collingwood's Intellectual Property Rights embodied in the Developments, including without limitation prosecuting and maintaining patent applications and patents and being joined as a party to an action brought by Collingwood to enforce such rights.
- 11.2. Cooperation. Each Party shall promptly notify the other Party of the development or conception of any subject matter arising under and in the performance of this Agreement prior to filing a patent application that discloses such subject matter.

Notwithstanding the foregoing, the Parties acknowledge that the provisions of Article 12 will continue to apply to any proposed disclosure that includes Confidential Information of the other Party.

11.3. License of Ovamed Intellectual Property Rights. Subject to the terms and conditions of this Agreement, Ovamed hereby grants to Collingwood and its Affiliates a license under any Ovamed Intellectual Property Rights in order to sell the Product either by Collingwood directly or through third parties.

12. CONFIDENTIAL INFORMATION.

12.1. Confidentiality.

`)

Except to the extent expressly authorized by this Agreement or otherwise agreed in writing, the Parties agree that, for the term of this Agreement and for five (5) years thereafter, each Party (the "Receiving Party") receiving any Confidential Information of the other Party (the "Disclosing Party") hereunder will keep such Confidential Information confidential and will not publish or otherwise disclose or use such Confidential Information for any purpose other than as provided for in this Agreement, except for Confidential Information that the Receiving Party can establish:

- (a) was already known by the Receiving Party (other than under an obligation of confidentiality) at the time of disclosure by the Disclosing Party and the Receiving Party has documentary evidence to that effect;
- was generally available to the public or otherwise part of the (b) public domain at the time of its disclosure to the Receiving Party;
- (c) became generally available to the public or otherwise part of the public domain after its disclosure or development, as the case may be, other than through any act or omission of the Receiving Party or any of its Affiliates;
- (d) was disclosed to the Receiving Party, other than under an obligation of confidentiality, by a Third Party who had no obligation to the Disclosing Party not to disclose such information to others; or
- (e) was independently discovered or developed by or on behalf of the Receiving Party without the use of any Confidential Information belonging to the Disclosing Party and the Receiving Party has documentary evidence to that effect.
- **(f)** is necessary to prepare and/or conduct litigation

Authorized Disclosure.

Notwithstanding the foregoing provisions of Section 12.1, each Party may disclose Confidential Information belonging to the other Party (i) to employees or Approved Subcontractors of the disclosing Party to the extent such disclosure is necessary for the disclosing Party to perform its obligations under this Agreement, or (ii) to the extent such disclosure is necessary, in the reasonable opinion of such Party's legal counsel, to prosecute or defend litigation or to comply with applicable governmental laws or regulations (including, but not limited to, securities laws and regulations), or (iii) to the extent such disclosure is necessary for any financing or corporate partnering activity of either parties provided that disclosure will be done under a signed CDA in a form substantially in accordance with the provisions of this clause. In the event a Party deems it necessary to disclose to a third party any Confidential Information belonging to the other Party, pursuant to this Section 12.2, the Disclosing Party will to the extent possible give reasonable advance notice of such disclosure to the other Party and take reasonable measures to ensure, including without limitation redacting portions of this Agreement prior to disclosure, as reasonably requested by the other Party, and ensuring that such third party is bound by and complies with the confidentiality terms of this Agreement.

12.3. No Confidential Information of Other Parties.

Each Party represents and warrants to the other that it has not used and will not use in the course of its performance hereunder, and will not disclose to the other, any confidential information of any third party, unless it is expressly authorized in writing by such third party to do so.

12.4. Equitable Relief.

Each Party agrees that the other Party would be irreparably injured by a material breach of the confidentiality and nonuse provisions of this Agreement by the breaching Party or by other parties to whom such Party has disclosed Confidential Information, that monetary remedies would be inadequate to protect the other Party against any actual or threatened material breach of the provisions of this Article 12 by the breaching Party or by such other authorized third parties, without prejudice to any other rights and remedies otherwise available to the other Party, the breaching Party agrees, upon proof of any such actual or threatened material breach, to the granting of equitable relief, including injunctive relief and specific performance. It is further understood and agreed that no failure or delay by either Party in exercising any right, power or privilege hereunder shall operate as a waiver thereof, nor shall any single or partial exercise thereof preclude any other or further exercise thereof or the exercise of any other right, power or privilege hereunder.

13. MISCELLANEOUS.

13.1. Correspondence and Notices.

All notices or other communications to a Party required or permitted hereunder will be in writing and will be delivered personally or by facsimile (receipt confirmed) to such Party (or, in the case of an entity, to an executive officer of such party) or will be given by certified mail, postage prepaid with return receipt requested, addressed as set forth below in this Section 13.1. Each Party may change its respective above-specified recipient and/or mailing address by notice

to the other Party given in the manner herein prescribed. All notices will be deemed given on the day when actually delivered as provided above (if delivered personally or by facsimile) or on the day shown on the return receipt (if delivered by mail).

All correspondence to Collingwood shall be addressed as follows:

Collingwood Pharmaceuticals, Inc. 787 Seventh Avenue
New York, NY 10019
Attn: Frank Taffy
Tel: (212) 554-4385

Fax: (212) 554-4355

With a copy to:

Hemmie Chang, Esq. Ropes & Gray LLP One International Place Boston, MA 02110 Tel: (617) 951-7317 Fax: (617) 951-7050

All correspondence to Ovamed shall be addressed as follows:

Ovamed GmbH
Kiebitzhörn 33-35
22885 Barsbüttel
Germany
Attention: Detley Goj
Tel: +49-40-67 50 95-0

With a copy to:
Klaus Lodigkeit
c/o Vorberg Rechtsanwälte
Rappstraße 16
20146 Hamburg
Germany

13.2. Compliance with the Laws; Permits and Licenses.

Each Party agrees that it will, in fulfilling its obligations under this Agreement, materially comply with all applicable laws including, but not limited to statutes, codes, rules, regulations, ordinances, judgments and decrees, now or hereafter in effect. Collingwood agrees that it will materially comply with all applicable laws including, but not limited to statutes, codes, rules,

regulations, ordinance, judgments and decrees, now or hereafter in effect related to the development, manufacture and marketing of the Product. Collingwood also represents and warrants that it has all governmental and regulatory licenses and permits necessary to operate its facilities and fulfill its obligations under this Agreement. Ovamed also represents and warrants that it has all United States and any other governmental and regulatory licenses and permits necessary to operate its facilities and fulfill its obligations under this Agreement. Failure to comply with this Section 13.2 will be a material breach of the Agreement.

13.3. Assignment.

This Agreement and the rights and duties appertaining hereto may not be assigned by either Party without first obtaining the written consent of the other, which consent shall not be unreasonably withheld. Any such purported assignment, without the written consent of the other Party, shall be null and of no effect. Notwithstanding the foregoing, Collingwood may assign this Agreement without the consent of Ovamed (i) to a purchaser, merging or consolidating corporation, or acquirer of substantially all of Collingwood's assets or business and/or pursuant to any reorganization qualifying under section 368 of the Internal Revenue Code of 1986 as amended, as may be in effect at such time, or (ii) to an Affiliate.

13.4. Force Majeure.

Neither Party shall be liable to the other for delay or failure in the performance of the obligations on its part contained in this Agreement if and to the extent that such failure or delay is due to circumstances beyond its control that it could not have avoided by the exercise of reasonable diligence, including without limitation, acts of God or of the public enemy, acts of the government in either its sovereign or contractual capacity, acts of terrorism, fires, floods, war, earthquakes, epidemics, quarantine restrictions, strikes, freight embargoes, unusually severe weather, the failure of Ovamed's suppliers or carriers to meet their contractual obligations, or if necessary raw material is unavailable (each a "Force Majeure Event"). The Party relying on this Section will notify the other Party promptly in the event such circumstances arise, giving an indication of the likely extent and duration thereof, and will use all commercially reasonable efforts to resume performance of its obligations as soon as practicable; provided, however, that neither Party shall be required to settle any labor dispute or disturbance. During the period that the performance by one of the Parties of its obligations under this Agreement has been suspended by reason of an event of Force Majeure, the other Party may likewise suspend the performance of all or part of its obligations hereunder to the extent that such suspension is commercially reasonable.

13.5. Use of Name.

Except as required by law, neither Party will use any trade name, trademark or service mark of the other Party, or of any of the other Party's Affiliates, in any advertising, promotional or sales literature, offering materials, business plan or any other form of publicity without the other Party's prior written consent.

13.6. Language of the Agreement.

The language of this Agreement shall be English and the parties hereby waive, and agree that this Agreement shall be valid and enforceable notwithstanding, any requirement that it be written in or translated into any language other than English. If, for any reason, this Agreement is translated into a language other than English, the English language version shall be controlling for all purposes.

13.7. UN Convention on Contracts for Sale of Goods.

The parties expressly agree that the United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Agreement.

13.8. Amendment.

No amendment, modification or supplement of any provision of this Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer of each Party.

13.9. Waiver.

No provision of the Agreement shall be waived by any act, omission or knowledge of a Party or its agents or employees except by an instrument in writing expressly waiving such provision and signed by a duly authorized officer of the waiving Party.

13.10. Severability.

If any clause or portion thereof in this Agreement is for any reason held to be invalid, illegal or unenforceable, the same shall not affect any other portion of this Agreement, as it is the intent of the Parties that this Agreement shall be construed in such fashion as to maintain its existence, validity and enforceability to the greatest extent possible. In any such event, this Agreement shall be construed as if such clause of portion thereof had never been contained in this Agreement, and there shall be deemed substituted therefore such provision as will most nearly carry out the intent of the Parties as expressed in this Agreement to the fullest extent permitted by applicable law.

13.11. Descriptive Headings.

The descriptive headings of this Agreement are for convenience only and shall be of no force or effect in construing or interpreting any of the provisions of this Agreement.

13.12. Governing Law.

This Agreement, the rights of the Parties and all claims arising under or in connection herewith, shall be governed by and interpreted in accordance with the substantive laws of Germany, without regard to conflict of law principles thereof that would cause the application of the laws of any other jurisdiction.

13.13. Jurisdiction; Venue; Service of Process.

13.13.2. <u>Venue</u>. Each Party agrees that for any Action between the parties arising in whole or in part under or in connection with this Agreement, any Action brought shall be brought in Germany.

13.14. Entire Agreement.

This Agreement and the Exhibits attached hereto constitutes and contains the complete, final and exclusive understanding and agreement of the Parties and cancels and supersedes any and all prior negotiations, correspondence, understandings and agreements, whether oral or written, between the Parties respecting the subject matter hereof and thereof.

13.15. Conflicts.

The Parties agree that, to the extent there is an inconsistency between the terms of this Agreement and the terms of the Sublicense, the terms of the Sublicense shall govern.

13.16. Independent Contractors.

Both Parties are independent contractors under this Agreement. Nothing herein contained shall be deemed to create an employment, agency, joint venture or partnership relationship between the Parties hereto or any of their agents or employees, or any other legal arrangement that would impose liability upon one Party for the act or failure to act of the other Party. Neither Party shall have any express or implied power to enter into any contracts or commitments or to incur any liabilities in the name of, or on behalf of, the other Party, or to bind the other Party in any respect whatsoever.

13.17. Counterparts.

This Agreement may be executed in any number of counterparts, each of which need not contain the signature of more than one Party but all such counterparts taken together shall constitute one and the same agreement.

[Signature page follows.]

IN WITNESS WHEREOF, the parties hereto have as of the Effective Date duly executed this Agreement, including the attached Exhibits that are incorporated herein and made a part hereof.

COLLINGWOOD PHARMACEUTICALS, INC.

OVAMED GMBH

By:_ Name:

Title:

Exhibit A

Specifications for TSO

Parameters	TSO specification	

Vial		
Name and address of manufacture	er:	
Physical description:		
Size:		
Closure System		
Product name:		
Name and address of manufacture	er:	
Physical description:		
Çiya:		

Exhibit B

Development and regulatory work to be performed by Ovamed

Exhibit C

Raw Materials Index

Exhibit D

TSO US-Specification

Parameters	Specification
· · · · · · · · · · · · · · · · · · ·	
}	

Exhibit E

Clinical Plan for Product